

**NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)**

**HERBAL MEDICINES AND RELATED PRODUCTS (REGISTRATION) REGULATIONS 2018**

**COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 DAYS.**

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**Commencement**:

**In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Sections 5 and 30 of the NAFDAC Act Cap N1 LFN 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and of all the powers enabling it in that behalf, THE GOVERNING COUNCIL OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL with the approval of the Honourable Minister of Health hereby makes the following Regulations:-**

1. **Scope:**

These Regulation prescribe the minimum requirements for the registration of herbal medicines and related products manufactured, imported, exported, distributed, advertised, sold, and used in Nigeria.

1. **Prohibition.**

No herbal medicine or related product shall be manufactured, imported, exported, distributed, advertised, sold or used in Nigeria unless it has been registered in accordance with the provisions of these regulations.

1. **Exceptions**:

Notwithstanding the provisions of Regulation 2, the Agency may grant a permit for the importation or manufacture of samples of herbal medicines and related products for the purpose of clinical trial or any such process as may be approved by the Agency and the importation or manufacture shall be in accordance with the conditions specified in the permit.

1. **Application for Registration .**
2. Application for the registration of a herbal medicine and related product shall be made by filing an application and supported with relevant documents in such form as the Agency may, from time to time, prescribe and shall-
3. contain the particulars and description of the herbal medicine and related product, in respect of which the application is made;
4. be accompanied by such fee as the Agency may, from time to time, prescribe.
5. The product particulars and description shall be detailed enough to consist of all administrative and technical information in sufficient details as may be required to permit the Agency make a knowledgeable judgment about the product.
6. The Agency, in considering an application-
7. may ask the applicant to supply such other information as it may require to enable it to reach a decision on the application;
8. shall satisfy itself that there is need to have the herbal medicine and related product registered in Nigeria.
9. The registration of a herbal medicine and related product under these Regulations shall, unless cancelled earlier, be valid for a period of two or five years as may be deem fit by the Agency; and may be renewed.
10. The Agency shall, from time to time, publish list of registered products on the Agency’s official website, notifying the registration of a herbal medicine and related product.
11. The Agency may refuse to register a product under Regulation 3(2) of these Regulations for any of the following reasons, unless the requirement has been waived;
12. if the outcome of review of information provided by the applicant in support of the product registration application showed that the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the herbal medicine and related product are inadequate to ensure and preserve its identity, strength, quality, and purity consistently.
13. unsatisfactory laboratory report for the product under consideration
14. unsatisfactory GMP inspection report
15. product labelling in contravention of Agency’s Herbal Medicine and Related Product Labelling regulations
16. **Penalty.**
17. A person who contravenes any of the provisions of these Regulations is guilty of an offence and liable on conviction:-
18. In the case of an individual, to imprisonment for a term not exceeding two years or to a fine not exceeding N50,000 or to both such imprisonment and fine; or
19. in the case of body corporate, to a fine not exceeding N100, 000.
20. Where an offence under these Regulations is committed by a body corporate or firm or other association of individuals every:-
21. director, manager, secretary or other similar officer of the body corporate; or
22. partner or officer of the firm; or
23. trustee of the body concerned; or
24. person concerned in the management of the affairs of the association; or
25. person who was purporting to act in a capacity referred to in paragraphs 5.1 (1-4) of this regulations, is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.
26. **Forfeiture**

 In addition to the Penalty specified in Regulations 5 of these Regulations, a person convicted of an offence under these Regulations shall forfeit to the Agency the herbal medicine or related product and whatsoever is used in connection with the commission of the offence.

1. **Interpretation.**

In these regulations, unless the context otherwise requires:

 **"Agency"** means National Agency for Food and Drug Administration and Control; and

**"Herbal Medicines and Related Products"** means:

1. finished and labelled medicinal product containing plant and their preparation presented with therapeutic or prophylactic claim and includes all preparations containing a plant material in part or wholly.
2. finished and labelled medicinal product containing only animal material in part or wholly and their preparation presented with therapeutic or prophylactic claim;
3. finished and labelled medicinal product containing only inorganic minerals and their preparations presented with prophylactic or therapeutic claim;
4. preparation or admixture of herbal, animal and mineral medicinal products manufactured, sold or advertised for use in the diagnosis, treatment, mitigation or prevention of any disease, disorder ,abnormal physical state or the symptom thereof, in man or animal; and
5. preparation or admixture used for restoring, correcting or modifying organic functions in man or in animal.
6. **Repeal of Herbal Medicines and Related Products (Registration) Regulations 2005**
	1. The Herbal Medicines and Related Products (Registration) Regulations 2018 is hereby repealed.
	2. The repeal of these Regulations specified in Regulation 8.1 shall not affect anything done or purported to be done under the repealed Regulations.
7. **Citation**

These Regulations may be cited as the Herbal medicines and Related Products (Registration) Regulations 2018.

MADE at Abuja this…………………………day of………………………2018

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**Inuwa Abdulkadir Esq**

**Chairman Governing Council**

**National Agency for Food and Drug Administration and Control (NAFDAC)**